#5 11/24/99
Translation

PATENT
171-613P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicants: Takanori OKA

Application No. 09/214,723 Group: 1653

Filed: January 11, 1999 Examiner: A. Pawul

For: NUCLEIC ACID ASSAY PROCESS AND ASSAY KIT

LETTER SUBMITTING ENGLISH LANGUAGE TRANSLATION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

November 18, 1999

Sir:

Attached hereto is a copy of the English language translation of the International Preliminary Examination Report in connection with the above-identified application. All of the references cited in the International Preliminary Examination Report Translation were filed in an Information Disclosure Statement on January 11, 1999. Please make the Report a part of the filewrapper of the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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GMM/CAM/jao
171-613P

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

To:

KOJIMA, Takashi
Ginza Morisawa Building, 3F
13-19, Ginza 2-chome
Chuo-ku
Tokyo 104
JAPON

Date of mailing (day/month/year) 12 October 1999 (12.10.99)	
Applicant's or agent's file reference FAP-1956	**IMPORTANT NOTIFICATION**
International application No. PCT/JP97/02370	**International filing date** (day/month/year) 09 July 1997 (09.07.97)
Applicant WAKUNAGA PHARMACEUTICAL CO., LTD. et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

EP,CA,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

JP

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Luis Hernandez

Telephone No. (41-22) 338.83.38

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FAP-1956	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP97/02370	International filing date (*day/month/year*) 09 July 1997 (09.07.1997)	Priority date (*day/month/year*) 11 July 1996 (11.07.1996)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68, C12N 15/11		
Applicant WAKUNAGA PHARMACEUTICAL CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19 December 1997 (19.12.1997)	22 September 1998 (22.09.1998)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP97/02370

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☒ the international application as originally filed.

☐ the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☐ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

International application No.
PCT/JP97/02370

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-10	NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations

Claims 1-10 do not appear to contain an inventive step based on document 1 [Anal. Biochem. 205 (2) (1992) pages 193-199], document 2 (WO, 95-02068, A), document 3 (JP, 6-178700, A), document 4 [Cancer Res. 51 (13) (1991) pages 3497-3502], document 5 (WO, 911-3075, A), document 6 (JP, 5-184396, A), and document 7 [DNA Diagnosis: Clinical Applications of Molecular Biology (1989) pages 105-109] as cited in the ISR.

The detection of genes by competitive hybridization is described in document 1 and document 2, the modification of probes to detect genes with biotin and DNP is described in document 6 and document 7, and the selection of a concentration to essentially optimize the sensitivity of the method for measuring the relative quantities of reagents used is described in document 3. Therefore, in the detection method described in document 1 and document 2, persons skilled in the art can easily conceive of modifying probes with biotin and DNP as described in document 6 and document 7, and selecting a concentration of reagents for measuring with the probes to optimize the sensitivity as described in document 3.

The determination of a specific sequence for K-ras and its mutant forms is described in document 4 and document 5. Therefore, no particular difficulty is found, even if these genes are specified as the objects to be detected in the above method.